

II. Remarks

A. Examiner Interview:

Applicants' attorneys greatly appreciate the courtesy that was extended by the Examiner during the office interview conducted on October 20, 2004. The Examiner indicates that a separate record of the substance of the interview is not necessary in view of the Examiner Interview Summary.

B. Status of the Claims:

Claims 1, 5-7, 10-20, 41-42, 45, 47-54, 56-57, 59-62, and 64-76 are currently pending and under examination. Claims 2-4, 8-9, 21-40, 43-44, 46, 55, 58, and 63 have been cancelled. No intention is implied to dedicate to the public any subject matter taught in the disclosure or previously claimed by way of this amendment. Applicants expressly reserve the rights to prosecute the subject matters in the cancelled claims in one or more continuations or divisional applications.

Claims 1, 5, 6, 7, 19, 20, 41, 60, 61, 62, 64, 65, 66, 69, 72, 74, and 75 have been amended to recite the term "phage particle" or to recite the correct claim number in the case of dependent claims. Support for the claim amendments can be found throughout the specification and in the claims as originally filed. No new matter is introduced in the claim amendments, and entry thereof is respectfully requested.

C. Claim Objections:

Claims 1, 21, 41, 62, and their respective dependent claims are objected to as they encompass non-elected embodiments. All claims currently pending are drawn to the elected embodiments only. This objection is therefore overcome.

D. Claim Rejections:

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1-2, 4-5, 10-18, 21-22, 24-25, 30-45, and 47-76 stand rejected under 35 U.S.C §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states that it would be unpredictable for a skilled artisan to envision a sufficient number of specific embodiments in the claimed genus of “genetic packages.”

Applicants submit that the specification fully meets the criteria of written description under 35 U.S.C §112, first paragraph. The specification provides considerable direction and guidance on how to construct the claimed adaptor display system for displaying an exogenous polypeptide on a variety of genetic packages, including for example, bacterial cells, phage particles, viral particles, and spores. In particular, the specification teaches and exemplifies the structures of the expression vector as well as the helper vector of the claimed adaptor-display system, and further details the methods for selecting and assembling the individual components contained therein (see, e.g., paragraphs 112-174). The specification has provided more than 10 different genetic packages, including various types of phages (filamentous or non-filamentous, see, e.g., paragraphs 115-122, examples 1-6) and bacterial display system including bacterial cells and spores (see, e.g., paragraphs 144-152). A specification satisfies

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the written description requirement even if it does not describe all species that the claim encompasses. *Cordis Corp. v. Medtronic Ave., Inc.* 339 F3d. 1352 (Fed. Cir. 2003). Here, Applicants have disclosed more than an adequate number of species to support the genus of genetic packages.

By contrast, the Office Action fails to set forth a *prima facie* case of lack of written description because it fails to set forth the reasons as to why one skilled in the art would consider the genus unpredictable given the ample guidance and working examples provided by the specification. In fact, many forms of genetic packages are known and employed in the art at the time of the invention. Among them are adenovirus (see, e.g., U.S. Patent No. 5,770,442), Herpes Simplex Virus (Desai et al. *Journal of Virology*, (1998) 72:(9) 7563-7568), baculovirus (see, e.g., references described in the background section of Kaba et al. *Protein Engineering*, (2003) 16:(1) 73-78), bacterial and yeast cells, and phages of filamentous or non-filamentous nature. Given the wealth of knowledge in the art and the detailed instruction provided by the instant specification, it is apparent that one skilled in the art can readily practice the claimed invention to display exogenous polypeptide on a variety of genetic packages. Such person can also readily recognize that Applicants were in possession of the genus of genetic packages.

While Applicants do not agree with this rejection and in no way acquiesce with this rejection, the independent claims 1, 41, 62, 66, 72 and hence their respective dependent claims have been amended to recite “phage particles.” These claim amendments are introduced merely in order to expedite the prosecution without prejudice. Applicants

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expressly reserve the rights to prosecute the subject matters of the claims as originally presented. Applicants respectfully submit that this rejection is moot.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner also rejects claims 1 and 41 and their respective dependent claims under 35 U.S.C §112, second paragraph, as allegedly being indefinite. Claims 1 and 41 have been amended to delete the term “any.” The amendments avoid unintended ambiguity, if any, and clearly point out that the vector is devoid of outer-surface sequences encoding functional outer-surface proteins. Therefore, this rejection is overcome.

Rejection Under 35 U.S.C. §102(b)

The Examiner rejects claims 21-27, 30, 61-64 under 35 U.S.C. §102(b) as allegedly being anticipated by Krebber et al. (FEBS Letters, 1995, Vol. 377, pages 227-231). Applicants respectfully traverse.

A reference is anticipatory if it describes each and every element of a claim. Krebber et al. does not meet this requirement. Krebber describes a single vector system, whereas the claimed display system comprises two components, namely a helper vector and an expression vector. Each of these two components includes features distinct from Krebber’s only vector. For instance, the expression vector lacks sequences that encode functional outer-surface proteins of the genetic package, but it contains sequences encoding the displayed polypeptide that is fused in-frame to an adaptor. By contrast, the helper vector comprises outer-surface

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sequences necessary for packaging the genetic package, wherein at least one of the outer-surface sequences is fused in-frame to another adapter.

In an effort to advance the issuance of the remaining claims, claims 21-40 drawn to the helper vector embodiments have been cancelled without prejudice. Applicants fully reserve their rights to prosecute the subject matters of the cancelled claims in a subsequent continuation application.

Finally, because Krebber et. al. does not meet the requirements of both or either component of the claimed display system, the method of using the claimed display system having these components (claim 60) and the displayed products (claim 61-64) are also novel. This rejection therefore should be withdrawn.

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III. Conclusion

It is submitted that the present application is in form for allowance, and such action is earnestly requested. Should the Examiner have any questions, please contact the undersigned attorney.

The Commissioner is authorized to charge any additional fees which may be required, including but not limited to petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 26050-712.201).

Respectfully submitted,

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